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LETTERS PATENT

STANDARD PATENT

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I, Fatima Beattie, the Commissioner of Patents, grant a Standard Patent with the following particulars:

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Fatima Beattie
Commissioner of Patents

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The claims defining the invention are as follows:

1. A method for preparing a composition of $F(ab')_2$ antibody fragments that is substantially free of whole antibodies, the method comprising the steps of:

(a) generating a source of antibodies by immunising animals with a complex antigenic mixture of animal venom, extracting blood plasma that is the source of antibodies and contacting with pepsin at a pH of 3.2 ± 0.2 under conditions to prepare an antibody digest containing $F(ab')_2$ fragments and being completely free of non-hydrolyzed antibodies;

(b) treating said digested antibodies by two steps of ammonium sulphate precipitation, with at least one step at about 16% to about 22% weight by volume of ammonium sulphate for at least 30 minutes at a temperature of 55 °C ± 4 °C , next cooling to approximately 8 °C ± 4 °C for at least two hours;

(c) clarifying the solution by filtering at 12, 8, 4 or 0.22 μ;

(d) subjecting the obtained solution to a second precipitation at about 32% to about 38% weight by volume of ammonium sulphate at about pH 6.8 ± 0.5, next leaving the solution to settle for at least 12 hours in refrigeration;

(e) centrifuging the resulting suspension to eliminate the supernatant and recover the paste of $F(ab')_2$ fragments precipitated in step (d);

(f) subjecting the obtained paste of $F(ab')_2$ fragments to dialysis to eliminate salts and low weight components and

(g) passing the solution through a sterile filter

2. The method of claim 1, wherein said venom is produced by a scorpion.

3. The method of claim 1, wherein said venom is produced by a snake.

4. The method of claim 1, wherein said venom is produced by a spider.

5. The method of claim 1 or claim 2, wherein the venom is selected from the group of scorpions of the taxonomic family Butidae and is selected one of the group consisting of: *Centruroides elegans-elegans, Centruroides exilicauda, Centruroides infamatus-infamatus, Centruroides limpidus-tecomanus, Centruroides limpidus-limpidus, Centruroides suffusus.*

6. The method of claim 1 or claim 3, wherein the venom is selected from one of the snake genera: Bothrops, Crotalus, Agkistrodon, Lachesis Sistrurus, or the species Micrurus nigrosinctus.

7. The method of claim 1 or claim 4, wherein the venom is from the spider species: *Lactrodectus mactans.*

8. The method of any one of claims 1 to 7, wherein the obtained composition of $F(ab')_2$ fragments is free of albumin, free of whole antibodies and free of viruses and pyrogens.

9. A composition of $F(ab')_2$ fragments having features a, b and c as follows:

(a) the $F(ab')_2$ fragments are produced by the method of any one of claims 1 to 8,

(b) the $F(ab')_2$ fragments are free of whole antibodies, free of albumin, free of viral particles, and free of pyrogens,

(c) the $F(ab')_2$ fragments are polyclonal, and capable of neutralising all the antigenic determinants present in complex animal venoms utilized to generate the source of antibodies of step (a).

10. The composition of claim 9 which includes a pharmaceutically acceptable carrier.

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